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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Sean T. O'Mara

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EXAMINER

DIXON, ANNETTE FREDRICKA

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/086,940	Applicant(s) O'MARA, SEAN T.	
	Examiner Annette F. Dixon	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 66-71,80-90,92-111,121-124 and 126-129 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 66-71,80-90,92-111,121-124 and 126-129 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 November 2007 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response to the request for continued examination filed on June 23, 2008. Examiner acknowledges claims 66-71, 80-90, 92-111, 121-124 and 126-129 are pending in this application with claims 66, 80, 90, 92, 94, 96-99, 101-109, 11, 121-123 having been currently amended, claims 127-129 having been newly added, and claims 1-65, 72-79, 91, 112-120, and 125 having been cancelled.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 23, 2008 has been entered.

Drawings

3. The drawings are objected to because Figure 1A discloses one circle within another circle to represent element 102 rather than one circle. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing

should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 66, 71, 80, 85, 86, 88-90, 92, 94, 96, 99-102, 109, 110, and 127-129 are rejected under 35 U.S.C. 102(b) as being anticipated by Cox (4,471,776).

As to Claims 80, 96, 99, 109, and 110, Cox discloses an intubation device, comprising an intubation placement device (68) having a bendable distal end configured to be introduced through a set of vocal cords (Column 6, Lines 39-40, and Figure 8); a intubation tube (12) having a distal end and a proximal end; and a stopper (70)

configured to removably secure a proximal end of the placement device (68) to a proximal end of the intubation tube (12) extending inside the intubation tube (12) and the distal end of the placement device (68) out of the distal end of the intubation tube (12). (Figures 3 and 8).

As to Claims 85, 86, and 100 Cox discloses the intubation tube placement device (68) is malleable and bent to the desired curved configuration. (Column 4, Lines 59-66).

As to Claims 88, 89, and 127, Cox discloses the distal end of the intubation tube placement device (68) includes an anti-perforation device (72) that serves a tactile accentuator to facilitate the insertion of the intubation placement device (18) into the internal passageway (66 of the intubation tube (12). (Column 6, Lines 39-45).

Regarding the detection of the cartilaginous rings, as the tactile accentuator (72) extends beyond the intubation tube (12), the cartilaginous rings (seen Figure 8) are detected during intubation.

As to Claim 101, Cox discloses the intubation tube (12) has a rounded end (Figure 2).

As to Claim 102, Cox discloses the tip of the intubation tube (12) has a diameter approximately equal to the diameter of the placement device (68). (Figure 3).

As to Claims 66, 71, 90, 94, Cox discloses an apparatus where the method of using the apparatus is inherent in the use of the apparatus. Cox discloses an intubation device, comprising an intubation placement device (68) having a bendable distal end configured to be introduced through a set of vocal cords (Column 6, Lines 39-40, and Figure 8); a intubation tube (12) having a distal end and a proximal end; and a stopper

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(70) configured to removably secure a proximal end of the placement device (68) to a proximal end of the intubation tube (12) extending inside the intubation tube (12) and the distal end of the placement device (68) out of the distal end of the intubation tube (12). (Figures 3 and 8). Cox discloses the distal end of the intubation tube placement device (68) includes an anti-perforation device (72) that serves a tactile accentuator to facilitate the insertion of the intubation placement device (18) into the internal passageway (66) of the intubation tube (12). (Column 6, Lines 39-45). Regarding the detection of the cartilaginous rings, as the tactile accentuator (72) extends beyond the intubation tube (12), the cartilaginous rings (seen Figure 8) are detected during intubation

As to Claims 92 and 129, Cox discloses the stopper (70) is partially and removably received into the intubation tube (12) via the connector (64). (Figures 2, 3, and 7, and Column 6, Lines 28-38).

As to Claim 128, Cox discloses the stopper (70) is partially and removably received into the intubation tube (12) via the connector (64) (Figures 2, 3, and 7, and Column 6, Lines 28-38) and is secured into the oral cavity (Figure 8).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 83 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (4,471,776) in view of Burkus et al. (6,743,234).

As to Claim 83, Cox discloses the intubation placement device (68) is a shaft, yet Cox does not expressly disclose the shaft is a hollow tube. However, at the time the invention was made the use of hollow tubes was known. Specifically, Burkus teaches a shaft (384) in a medical device that may be made solid or hollow. Further, Burkus teaches the hollow tube reduces the weight of the shaft. (Column 14, Lines 27-30). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Cox to include a hollow tube as taught by Burkus to reduce the overall weight of the intubation tube placement device.

8. Claims 67-70, 84, and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (4,471,776) in view of Northway-Meyer (4,848,331).

As to Claim 68-70, 93, Cox discloses an intubation tube placement device, yet does not expressly disclose the use of suctioning materials. However, at the time the invention was made the use of suctioning materials formed within the intubation tube placement device was known. Specifically, Northway-Meyer, teaches the use of suctioning materials in intubation procedures for the purpose of removing secretions and blood. (Column 2, Lines 25-30). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Cox to include a suctioning materials as taught by Northway-Meyer for the purpose of clearing mucous and debris from the patient's respiratory tract.

As to Claim 67 and 84, Cox discloses an intubation tube placement device (68), yet does not expressly disclose the use of a fiber optic cable to extend into the placement device. However, at the time the invention was made the use of fiber optic cables in intubation was known. Specifically, Northway-Meyer, teaches the use of a fiber optic cable (276) for assisting in the placement of the intubation tube during difficult intubations (Column 2, Lines 15-35). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Cox to include the fiber optic cable as taught by Northway-Meyer, for the purpose of assisting the health care professional in the proper placement of the intubation device.

9. Claims 81, 82, 87, 97, 98, 111,121, and 123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (4,471,776) in view of Stuart (5,546,937)

As to Claims 81, 82, 97, 98, 111,121, and 123, Cox discloses the stopper (70) has a center hole configured to receive the intubation tube placement device (68), where the stopper (70) is partially and removably received into the intubation tube (12) via the connector (64). (Figures 2, 3, and 7, and Column 6, Lines 28-38). Yet, Cox does not expressly disclose the stopper to be made of rubber. However, at the time the invention was made the use of rubber in stopper was known. Specifically, Stuart teaches a plastic intubation tube placement device to increase the flexibility of the intubation tube placement device during operation. (Column 4, Lines 6-29, and Column 6, Line 49-55). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Cox to be made of a

plastic material, as taught by Stuart to provide more flexible intubation placement device for introduction into the body.

As to Claim 87, Cox discloses the intubation tube placement device (68) is used for medical procedures. (Abstract). Inherently, the device is made of a medical grade material. Yet, Cox does not expressly disclose the material is a polymer. However, at the time the invention was made the use of plastic intubation tube placement devices was known. Specifically, Stuart teaches a plastic intubation tube placement device to increase the flexibility of the intubation tube placement device during operation. (Column 4, Lines 6-29). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Cox to be made of a plastic material, as taught by Stuart to provide more flexible intubation placement device for introduction into the body.

10. Claims 95 and 103-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (4,471,776) in view of Parker (5,873,362)

As to Claims 95, 103, 106, 107, Cox discloses an intubation tube placement device (68) and an intubation tube (12), yet does not expressly disclose the formation of a plurality of ventilation holes on the intubation tube. However, at the time the invention was made the use of ventilation holes on intubation tubes was known. Specifically, Parker discloses the use of Murphy eyes (12)) for the purpose of ventilating the gases within the intubation tube (Column 6, Lines 6-10). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to

modify the device of Cox to include the holes on the intubation tube, as taught by Parker for the purpose of providing ventilation of the gases within the intubation tube.

As to Claim 104, Cox discloses an intubation tube yet does not expressly disclose the distal end of the intubation tube having a tapered end. However, at the time the invention was made the use of tapered ends on intubation tubes was known. Specifically, Parker teaches a tapered end (50) for the purpose of facilitating intubation of the intubation tube. (Column 5, Liens 20-22). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Cox to include a tapered end, as taught by Parker, to facilitate the intubation of the intubation tube into the patient.

As to Claim 105, Cox discloses the tip of the intubation tube (12) has a diameter approximately equal to the diameter of the placement device (68). (Figure 3).

As to Claim 108, Cox discloses a inflatable cuff (14) on the intubation tube (12). (Figures 2, 3, and 8). Further Parker discloses the orientation of the ventilation openings between the inflatable cuff and the distal end of the intubation tube. (Figures 1 and 6).

11. Claims 122, and 126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (4,471,776) in view of Evans et al. (5,250,033).

As to Claims 122, and 126, Cox discloses an intubation placement device having a stopper and an intubation tube, yet does not expressly disclose the use of a perforated edge to detach the stopper from the intubation tube. However, at the time the invention was made the use of perforated edges in the detachment of stoppers was

known. Specifically, Evans teaches the detachment of the adapter and the tube by a perforated edge (30) for the purpose of enabling the proper placement of the device to the targeted region (Figure 2, Column 3, Lines 32-61). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Cox to include the perforated edge, as taught by Evans for the purpose of ensuring the proper placement of the device within the body and to enable easy removal of the guide from the intubation tube.

12. Claim 124 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (4,471,776) in view of Stuart (5,546,937) as applied to claim 123 above, and further in view of Evans et al. (5,250,033).

As to Claim 124, the system of Cox/Stuart discloses an intubation placement device having a stopper and an intubation tube, yet does not expressly disclose the use of a perforated edge to detach the stopper from the intubation tube. However, at the time the invention was made the use of perforated edges in the detachment of stoppers was known. Specifically, Evans teaches the detachment of the adapter and the tube by a perforated edge (30) for the purpose of enabling the proper placement of the device to the targeted region (Figure 2, Column 3, Lines 32-61). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Cox/Stuart to include the perforated edge, as taught by Evans for the purpose of ensuring the proper placement of the device within the body and to enable easy removal of the guide from the intubation tube. Regarding the perforated

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limitation, Applicant is advised that the recitation of the perforation edge is directed to a process. Applicant is reminded patentably eight is only given to the end product in apparatus/product claims. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Response to Arguments

13. Applicant's arguments with respect to claims 66-71, 80-90, 92-111, 121-124 and 126-129 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Annette F Dixon
Examiner
Art Unit 3771

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